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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION; AMGEN MANUFACTURING, LIMITED; and HOFFMANN-LA ROCHE INC.;	Honorable Claire C. Cecchi, U.S.D.J.
Plaintiffs,	Civil Action No. 16 CV 1118 (CCC) (MF)
v.	
SANDOZ INC.; SANDOZ INTERNATIONAL GMBH; SANDOZ GMBH;	**DEFENDANT SANDOZ GMBH'S ANSWER, AFFIRMATIVE DEFENSES, AND DEMAND FOR JURY TRIAL**
Defendants.	CONTAINS DEFENDANTS' CONFIDENTIAL INFORMATION

Defendant Sandoz GmbH, by and through its undersigned attorneys, hereby submits this Answer and Affirmative Defenses to the Complaint filed by Immunex Corporation ("Immunex"), Amgen Manufacturing, Limited ("AML"), and Hoffman-LaRoche Inc. ("Roche", and collectively with Immunex and AML, "Plaintiffs"), dated February 26, 2016.

The Complaint improperly refers to "Sandoz" to include co-defendants Sandoz Inc. and Sandoz International GmbH, which are separate companies. All responses below are made solely on behalf of Sandoz GmbH, and no response is made to any allegation that is properly directed at any defendant other than Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies all allegations properly directed at other defendants.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Sandoz GmbH denies each and every allegation in Plaintiffs' Complaint except those expressly admitted below.

I. THE PARTIES

A. Plaintiffs

1. Immunex Corporation ("Immunex") is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly-owned subsidiary of Amgen Inc.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 1, and on that basis denies these allegations.

2. Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777. AML is a wholly-owned subsidiary of Amgen Inc.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2, and on that basis denies these allegations.

3. Hoffmann-La Roche Inc. ("Roche") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3, and on that basis denies these allegations.

B. Defendants

4. On information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, with its principal place of business at 100 College Road West, Princeton, New Jersey 08540. Upon information and belief, acting in concert with each of the other Defendants, Sandoz Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States. Upon information and belief, Sandoz Inc. is also the United States agent for Sandoz International GmbH and Sandoz GmbH for purposes including, but not limited to, filing regulatory submissions to and corresponding with the Food and Drug Administration ("FDA").

ANSWER: On information and belief, Sandoz GmbH admits that Sandoz Inc. is a corporation

organized and existing under the laws of the State of Colorado with its principal place of business at 100 College Road West, Princeton, New Jersey 08540. The remaining allegations contained in paragraph 4 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

5. Upon information and belief, Sandoz International GmbH is a corporation existing under the laws of the Federal Republic of Germany with its principal place of business at Industriestraße 25, 83607 Holzkirchen, Germany. Upon information and belief, acting in concert with each of the other Defendants, Sandoz International GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States.

ANSWER: On information and belief, Sandoz GmbH admits that Sandoz International has its principal place of business at Industriestaße 25, 83607 Holzkirchen, Germany. The remaining allegations contained in paragraph 5 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

6. Upon information and belief, Sandoz GmbH is a corporation existing under the laws of the Republic of Austria with its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. Upon information and belief, acting in concert with each of the other Defendants, Sandoz GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the State of New Jersey and throughout the United States.

ANSWER: Sandoz GmbH admits that it has its principal place of business at Biochemistraße 10, 6250 Kundl, Austria. Sandoz GmbH denies the remaining allegations in paragraph 6 as stated.

7. Upon information and belief, Sandoz GmbH operates as a subsidiary of Sandoz International GmbH.

ANSWER: Denied.

8. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the State of New Jersey and throughout the United States.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 8, to the extent they

are directed to it. The remaining allegations contained in paragraph 8 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B)

II. NATURE OF THE ACTION

9. This is an action for patent infringement arising under 35 U.S.C. § 271, including § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"). This action involves patents that cover etanercept (the active ingredient of the biologic drug product, ENBREL®), its method of manufacture, certain materials used in its manufacture, and certain therapeutic uses of etanercept. Immunex and AML (collectively, "Immunex/AML") and Roche bring this suit to enjoin Defendants from infringing their patents and to recover any damages resulting from Defendants' infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz GmbH admits this is an action for patent infringement under 35 U.S.C. § 271(e)(2)(C). Sandoz GmbH denies the remaining allegations contained in Paragraph 9 as stated.

10. The asserted patents are United States Patent Nos. 8,063,182 ("the '182 patent"), 8,163,522 ("the '522 patent"), 7,915,225 ("the '225 patent"), 8,119,605 ("the '605 patent"), and 8,722,631 ("the '631 patent") (collectively, "the patents-in-suit").

ANSWER: Sandoz GmbH admits that Plaintiffs' Complaint alleges infringement of U.S. Patent Nos. 8,063,182 ("the '182 patent"); 8,163,522 ("the '522 patent"); 7,915,225 ("the '225 patent"); 8,119,605 ("the '605 patent"); and 8,722,631 ("the '631 patent").

11. Roche is the owner of the '182 and '522 patents. Immunex is the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell ENBREL®.

ANSWER: Sandoz GmbH admits that Immunex is the owner of all commercial rights in the '182 and '522 patents. Sandoz GmbH denies the remaining allegations contained in Paragraph 11.

12. Immunex is the owner of the '225, '605, and '631 patents.

ANSWER: Sandoz GmbH admits the allegations contained in Paragraph 12.

13. Immunex has granted AML an exclusive license (or, with respect to the '182 and '522 patents, an exclusive sublicense) to the asserted patents.

ANSWER: Sandoz GmbH admits that Immunex granted AML an exclusive sublicense to the '182 and '522 patents. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 13, and on that basis denies these allegations.

14. On September 29, 2015, the FDA accepted Defendants' abbreviated Biologics License Application ("aBLA") pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as § 351(k) of the Public Health Service Act ("PHSA")), seeking authorization from the FDA to market a biosimilar version of Immunex's ENBREL® (etanercept) product.

ANSWER: On information and belief, Sandoz GmbH admits that on September 29, 2015, Sandoz, Inc. received notification from the FDA that Sandoz, Inc.'s BLA No. 761042 for etanercept, submitted under 42 U.S.C. § 262(k), was accepted for review. Sandoz GmbH denies the remaining allegations contained in Paragraph 14 as stated.

15. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. The abbreviated pathway (also known as "the (k) pathway") allows a biosimilar applicant (here Sandoz Inc.) to rely on the prior licensure and approval status of the innovative biological product (here ENBREL®) that the biosimilar purports to copy. Immunex is the sponsor of the reference product, ENBREL®, which is approved by the FDA for a number of different indications *(i.e.*, therapeutic uses).

ANSWER: Sandoz GmbH admits the allegations in the first sentence of Paragraph 15. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in the last sentence of Paragraph 15, and on that basis denies these allegations. The remaining allegations contained in Paragraph 15 are allegations of law or characterizations of the BPCIA that require no response from Sandoz GmbH, and Sandoz GmbH, therefore, denies these allegations.

16. Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2)(C) when they caused Sandoz Inc. to submit Defendants' aBLA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Defendants' etanercept product prior to the expiration of the asserted patents.

ANSWER: Sandoz GmbH admits that 35 U.S.C. § 271(e)(2)(C) states: "It shall be an act of infringement to submit—. . . (C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act . . . an application seeking approval of a biological product . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent before the expiration of such patent." On information and belief, Sandoz GmbH admits that on December 18, 2015, Plaintiffs sent Sandoz, Inc. a letter purporting to identify a list of patents under 42 U.S.C. § 262(*l*)(3)(A) for which Plaintiffs believed a claim of patent infringement could reasonably be asserted if Sandoz, Inc. engaged in the making, using, offering to sell, selling or importing into the United States Sandoz Inc.'s etanercept product, and that Plaintiffs' list includes the '182, '522, '225, '605, and '631 patents, among others. On information and belief, Sandoz GmbH further admits that Sandoz, Inc. has submitted BLA No. 761042 seeking approval to engage in the sale of Sandoz Inc.'s etanercept product before expiration of the '182, '522, '225, '605, and '631 patents, among others. Sandoz GmbH denies the remaining allegations contained in Paragraph 16.

17. If the FDA approves Defendants' aBLA, Defendants will also infringe one or more claims of each of the patents-in-suit, under 35 U.S.C. § 271(a), (b), or (g), should they engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Defendants' etanercept product.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 17.

III. JURISDICTION AND VENUE

A. Subject-matter Jurisdiction

18. This Court has subject-matter jurisdiction over Immunex/AML and Roche's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

ANSWER: Sandoz GmbH admits that this Court has subject matter jurisdiction over the patent infringement claims in Plaintiffs' Complaint under 28 U.S.C. §§ 1331 and 1338(a). Sandoz

GmbH denies the remaining allegations contained in Paragraph 18.

B. Sandoz Inc.

19. This Court has personal jurisdiction over Sandoz Inc. by virtue of the fact that, on information and belief, Sandoz Inc.'s principal place of business is in the District of New Jersey.

ANSWER: The allegations contained in Paragraph 19 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

20. Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH hold themselves out as a unitary entity and have represented to the public that their activities are directed, controlled, and carried out as a single entity.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 20.

21. For example, during prior litigation brought by Sandoz Inc. concerning the '182 and '522 patents, *see Sandoz Inc. v. Amgen Inc.,* 773 F.3d 1274 (Fed. Cir. 2014), Sandoz Inc. submitted a declaration by Rudiger Jankowsky which stated that he worked for "Sandoz." According to his LinkedIn profile, at the time Jankowsky worked for "Sandoz Biopharmaceuticals/Novartis" in Holzkirchen, Germany—the location of Sandoz International GmbH's principal place of business.

ANSWER: The allegations contained in Paragraph 21 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). .

22. As another example, during the same prior litigation brought by Sandoz Inc. concerning the '182 and '522 patents, Sandoz Inc. submitted a declaration by Karsten Roth which stated that he was employed by "Sandoz Inc." However, according to his LinkedIn profile, at the time of his declaration he was employed by "Sandoz" in the "Munich Area, Germany." Upon information and belief, [redacted]

ANSWER: The allegations contained in Paragraph 22 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

C. Sandoz International GmbH

23. Upon information and belief, Sandoz International GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States.

ANSWER: The allegations in Paragraph 23 are directed to another Defendant and therefore

require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

24. Upon information and belief, Sandoz International GmbH exercises considerable control over Sandoz Inc. with respect to biosimilar products, and approves significant decisions of Sandoz Inc. such as allowing Sandoz Inc. to act as the agent for Sandoz International GmbH in connection with preparing and filing Defendants' aBLA and to act as Sandoz International GmbH's agent in the United States. For example, the Sandoz Management Team includes "Richard Francis, Global Head of Sandoz," and "Peter Goldschmidt, President of Sandoz US and Head of North America." Upon information and belief, Mr. Francis is the head of Sandoz International GmbH, Mr. Goldschmidt is the President of Sandoz Inc. as well as the Head of North American Operations at Sandoz International GmbH, and Mr. Goldschmidt directly or indirectly reports to Mr. Francis.

ANSWER: The allegations contained in Paragraph 24 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

25. Upon information and belief, [redacted]

ANSWER: The allegations contained in Paragraph 25 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

26. In addition, Sandoz International GmbH and Sandoz Inc. hold themselves out as unitary entity and have represented to the public that the activities of Sandoz International GmbH and Sandoz Inc. are directed, controlled, and carried out as a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com attached hereto as Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

ANSWER: The allegations contained in Paragraph 26 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

27. Upon information and belief, Sandoz International GmbH is actively involved in planning Sandoz Inc.'s new products and filing Defendants' aBLA for the biosimilar product in dispute. For example, Sandoz Inc.'s President, Mr. Goldschmidt, is also the Head of North American Operations at Sandoz International GmbH.

ANSWER: The allegations contained in Paragraph 27 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

28. Upon information and belief, Sandoz International GmbH acted in concert with Sandoz Inc. to develop a biosimilar version of ENBREL®. Upon information and belief, Sandoz International GmbH acted in concert with, directed, or authorized Sandoz Inc. to file an aBLA seeking approval from the FDA to market and sell Defendants' biosimilar product in the State of New Jersey and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement. For example, Novartis AG, the ultimate corporate parent of both Sandoz International GmbH and Sandoz Inc., issued a press release on October 2, 2015, from Holzkirchen, Germany announcing that the FDA had accepted an application by "Sandoz" for biosimilar etanercept. *See* Press Release, Novartis, "FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept" (Oct. 2, 2015), https://www.novartis.com/news/media-releases/fda-accepts-sandoz-regulatory-submission-proposed-biosimilar-etanercept, attached hereto as Exhibit B. Upon information and belief, the press release announcing the FDA's acceptance of Defendants' aBLA, which is the subject of Plaintiffs' claims, was issued on behalf of Sandoz International GmbH.

ANSWER: The allegations contained in Paragraph 28 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

29. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz International GmbH. Upon information and belief, Sandoz International GmbH directly or indirectly manufactures, imports into the United States, or sells Defendants' biosimilar product that is the subject of the infringement claims in this action in New Jersey and throughout the United States.

ANSWER: The allegations contained in Paragraph 29 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

30. Additionally, and in the alternative, Immunex/AML and Roche allege that to the extent Sandoz International GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz International GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

ANSWER: The allegations contained in Paragraph 30 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

31. Upon information and belief, Sandoz GmbH collaborates with Sandoz Inc. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in New Jersey and in the United States.

ANSWER: Sandoz GmbH denies the allegations in Paragraph 32 to the extent they are directed

to it. The remaining allegations contained in Paragraph 32 are directed to another Defendant and therefore require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

32. Sandoz GmbH and Sandoz Inc. hold themselves out as a unitary entity and have represented to the public that the activities of Sandoz GmbH and Sandoz Inc. are directed, controlled, and carried out as a single entity. For example, Sandoz maintains an Internet website at the URL www.sandoz.com, attached hereto Exhibit A, which states that it is "the website of Sandoz International" and on which Sandoz states that all of the worldwide generic pharmaceutical businesses owned by Novartis operate "under one single global brand as known today: Sandoz."

ANSWER: Sandoz GmbH admits that Exhibit A contains the quoted statements. Sandoz GmbH denies the remaining allegations in Paragraph 32 to the extent they are directed to it. The remaining allegations contained in Paragraph 32 are directed to another Defendant and therefore require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

33. Upon information and belief, Sandoz GmbH is actively involved with planning Sandoz Inc.'s new biosimilar etanercept products and filing Defendants' aBLA for the biosimilar product in dispute. Title 42 U.S.C. § 262(k)(2)(A)(V) provides that a biosimilar application submitted to the FDA under the § 262(k) pathway "shall include" information demonstrating "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." Upon information and belief, [redacted] Therefore, upon information and belief, [redacted]

ANSWER: Sandoz GmbH admits that [redacted] Sandoz GmbH denies the remaining allegations in Paragraph 33 directed to it and allegations of law, including those concerning 42 U.S.C. § 262(k)(2)(A)(V), which require no response from Sandoz GmbH. To the extent the allegations in Paragraph 33 are directed to another Defendant, such allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

34. Upon information and belief, Sandoz GmbH acted in concert with Sandoz Inc. to

develop a biosimilar version of ENBREL®. Upon information and belief, Sandoz GmbH acted in concert with, directed, or authorized Sandoz Inc. to file an aBLA seeking approval from the FDA to market and sell Defendants' biosimilar product in the State of New Jersey and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 34 directed at it, and denies all allegations of law, which require no response from Sandoz GmbH. To the extent that the allegations contained in Paragraph 34 are directed to another Defendant, such allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

35. Upon information and belief, [redacted]

ANSWER: On information and belief, Sandoz GmbH admits that [redacted]" Sandoz GmbH denies the remaining allegations contained in Paragraph 35.

36. Upon information and belief, [redacted]

ANSWER: Sandoz GmbH admits that [redacted] Sandoz GmbH denies the remaining allegations contained in Paragraph 36.

37. Upon information and belief, the acts of Sandoz Inc. complained of herein were done, in part, for the benefit of Sandoz GmbH. Upon information and belief, Sandoz GmbH directly or indirectly manufactures, imports into the United States, or sells Defendants' biosimilar product that is the subject of the infringement claims in this action in New Jersey and throughout the United States.

ANSWER: Sandoz GmbH admits that the active pharmaceutical ingredient of the etanercept product that is the subject of BLA No. 761042 is manufactured at Sandoz GmbH's facilities. Sandoz GmbH denies the remaining allegations contained in Paragraph 37 that are directed to it. To the extent that the allegations in Paragraph 37 are directed to another Defendant, such

allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

38. Additionally, and in the alternative, Plaintiffs allege that to the extent Sandoz GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the State of New Jersey, Sandoz GmbH likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

ANSWER: The allegations contained in Paragraph 38 are allegations of law that require no response from Sandoz GmbH, but because they purport to be a basis of personal jurisdiction that does not exist as a matter of law, Sandoz GmbH denies them. Sandoz GmbH further states that, for purposes of this action only and in the interests of expediting a decision on the merits, Sandoz GmbH will not challenge personal jurisdiction over Plaintiffs' patent claims, but expressly reserves the right to context personal jurisdiction in any other case as to any party, including Plaintiffs.

D. Venue

39. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b). On information and belief, Defendants manufacture, seek regulatory approval to market, distribute, and sell pharmaceutical products, and market, distribute, and sell pharmaceutical products for use throughout the United States, including in this District.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 39, but for purposes of this action only will not challenge venue over Plaintiffs' patent claims against it.

IV. BACKGROUND

A. TNF and TNF Receptors

40. Tumor necrosis factor ("TNF") is a cell signaling protein that is involved in various biological effects that include the regulation of immune response, inflammation, and other processes. It was first identified as an agent that has cytotoxic effects on tumor cells, and hence was named "tumor necrosis factor." Overproduction of TNF in the body is also implicated in various autoimmune diseases and other inflammatory disorders.

ANSWER: Sandoz GmbH admits the allegations contained in Paragraph 40.

41. The biological effects of TNF can be mediated via specific receptors that are

found on the membranes of certain cells. TNF receptors on the surface of the cells can specifically bind to TNF. This binding can trigger reactions inside the cell, which can give rise to a number of different responses, including inflammation, cell growth, and cell death.

ANSWER: Sandoz GmbH the allegations contained in Paragraph 41.

42. Two cell membrane-bound receptors specific to TNF are sometimes referred to as the "p55 TNF receptor" and the "p75 TNF receptor."

ANSWER: Sandoz GmbH admits the allegations contained in Paragraph 42.

B. Immunex's Investment in ENBREL® (etanercept)

43. The active ingredient in ENBREL® is etanercept, a genetically engineered, non-naturally occurring fusion protein that binds to and inhibits TNF from binding to a TNF receptor.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 43, and on that basis denies these allegations.

44. The etanercept fusion protein was genetically engineered to fuse the extracellular region of the human p75 version of the TNF receptor with a portion of a human immunoglobulin heavy chain (*i.e.*, a portion of a human antibody).

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 44, and on that basis denies these allegations.

45. By binding to and inhibiting TNF from interacting with TNF receptors, ENBREL® can reduce certain inflammatory responses implicated in certain disorders such as rheumatoid arthritis, psoriasis, and psoriatic arthritis, and others.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 45, and on that basis denies these allegations.

46. The FDA has approved ENBREL® for the following indications: rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. The availability of ENBREL® represented a major advance in the treatment of these disorders.

ANSWER: Sandoz GmbH admits that ENBREL® is FDA approved for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH lacks knowledge or information sufficient to

form a belief about the truth of the remaining allegations contained in Paragraph 46, and on that basis denies these allegations.

47. Immunex conducted Phase I testing to determine whether ENBREL® was safe to administer to patients with rheumatoid arthritis; results published in 1993 indicated that it was. Immunex then conducted Phase II testing to begin determining whether ENBREL® improved symptoms of rheumatoid arthritis; results indicating that it did improve symptoms were published in 1996. Immunex conducted Phase III testing and invested a substantial amount of time and resources testing ENBREL® to demonstrate that it was safe and effective for certain disorders.

ANSWER: Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 47, and on that basis denies these allegations.

48. Based on the results of clinical testing in rheumatoid arthritis, Immunex filed Biologic License Application ("BLA") No. 103795. As a result, in November 1998, the FDA first approved ENBREL®, pursuant to BLA No. 103795, for the treatment of moderate to severe rheumatoid arthritis. Immunex holds the rights to BLA No. 103795.

ANSWER: On information and belief, Sandoz GmbH admits that the FDA approved ENBREL® in 1998 for the treatment of moderate to severe rheumatoid arthritis under BLA No. 103795. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 48, and on that basis denies these allegations.

49. Other clinical testing revealed that ENBREL® was safe and effective for certain additional diseases. Based on Immunex's further clinical testing, Immunex filed supplements to BLA No. 103795, requesting that ENBREL® be approved for certain additional indications. As a result, the FDA approved ENBREL® for the treatment of polyarticular juvenile idiopathic arthritis in 1999, psoriatic arthritis in 2002, ankylosing spondylitis in 2003, and plaque psoriasis in 2004. These approvals are the direct result of very significant investments by Immunex in the development and clinical trials of ENBREL®.

ANSWER: On information and belief, Sandoz GmbH admits that the FDA approved ENBREL® for the treatment of polyarticular juvenile idiopathic arthritis in 1999, psoriatic arthritis in 2002, ankylosing spondylitis in 2003, and plaque psoriasis in adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic

therapy or phototherapy in 2004. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 49, and on that basis denies these allegations.

C. Defendants' Abbreviated BLA

50. Defendants are piggybacking on the fruits of Immunex/AML and Roche's trailblazing efforts. Defendants have publicly announced that they filed their aBLA under the (k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States their etanercept product that they assert is a biosimilar version of Immunex's ENBREL®.

ANSWER: Sandoz GmbH admits that Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Sandoz Inc.'s etanercept product, which is biosimilar to the product that is the subject of BLA No. 103795. Sandoz GmbH denies the remaining allegations contained in Paragraph 50.

51. Defendants have also chosen to benefit from the clinical data generated by Immunex/AML's investments demonstrating the therapeutic indications for which ENBREL® is effective. Defendants issued a press release stating that "Sandoz is seeking approval for all indications included in the label of the reference product which is used to treat a range of autoimmune diseases including rheumatoid arthritis and psoriasis affecting approx. 1.3 million and 7.5 million people (respectively) in the US" (footnotes omitted). *See* Press Release, Novartis, "FDA accepts Sandoz regulatory submission for a proposed biosimilar etanercept" (Oct. 2, 2015), https://www.novartis.com/news/media-releases/fda-accepts-sandoz-regulatory-submission-proposed-biosimilar-etanercept, attached hereto as Exhibit B.

ANSWER: Sandoz GmbH admits that the document attached as Exhibit B to the Complaint contains the quoted language. To the extent that Paragraph 51 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). Sandoz GmbH denies the remaining allegations contained in Paragraph 51.

52. On information and belief, Defendants conducted clinical trials only for the use of their biosimilar drug product on psoriasis patients, despite the breadth of their request to the FDA for approval for other indications, such as rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis.

ANSWER: Sandoz GmbH admits that clinical trials for the use of Sandoz Inc.'s biosimilar etanercept drug product in patients with plaque psoriasis were conducted. To the extent that Paragraph 52 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). Sandoz GmbH denies the remaining allegations contained in Paragraph 52.

53. On information and belief, Defendants did not conduct any clinical trials on indications for which ENBREL® had not already been demonstrated to be safe and effective.

ANSWER: On information and belief, Sandoz GmbH has not conducted any clinical trials on indications for which ENBREL® has not already been demonstrated to be safe and effective. To the extent that Paragraph 53 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

54. On information and belief, the amino acid sequence of Defendants' etanercept fusion protein is the same amino acid sequence of the etanercept fusion protein in ENBREL®.

ANSWER: On information and belief, GmbH International admits the allegations contained in Paragraph 54.

55. On information and belief, Defendants have represented to the FDA that their etanercept product is biosimilar to Immunex's ENBREL®. As such, on information and belief, Defendants' etanercept product utilizes the same mechanism of action as ENBREL® for the conditions of use prescribed, recommended, or suggested in ENBREL®'s approved label. In addition, the route of administration, the dosage form, and the strength of Defendants' etanercept product are the same as those of Immunex's ENBREL®. *See* 42 U.S.C. § 262(k)(2)(A)(i).

ANSWER: Sandoz GmbH admits that the etanercept product that is the subject of BLA No. 761042 is biosimilar to the product that is the subject of BLA No. 103795 and that Sandoz Inc.'s BLA meets all of the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Sandoz GmbH denies the remaining allegations contained in Paragraph 55.

D. Defendants' Refusal to Comply with the BPCIA

56. Defendants have—for the second time—tried to reap the commercial benefits provided to biosimilar manufacturers under the BPCIA while seeking to avoid the obligations in

that same Act that Congress established to protect innovators such as Immunex/AML and Roche.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 56.

57. On October 19, 2015, which was, on information and belief, 20 days after the FDA notified Sandoz Inc. that its aBLA had been accepted for review, Sandoz Inc. provided Immunex with remote access to a Sandoz-hosted database of TIFF images, modified to include added confidentiality designations, that Sandoz Inc. represented to constitute its aBLA and information relating to the manufacturing process for Defendants' biosimilar product. The manner in which this database access was provided would not have allowed Immunex local access and evaluation except after manual download of the thousands of documents included therein, along with a folder-by-folder manual reconstruction of the database's directory structure. Sandoz Inc. did not provide a local copy of the database—including the necessary database load files and associated data—and an unaltered copy of the aBLA in the same electronic format as submitted to FDA until October 28, 2015.

ANSWER: The allegations contained in Paragraph 57 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

58. On November 9, 2015, determining that Sandoz had failed to provide complete information describing the processes used to manufacture the biological product that is the subject of Defendants' aBLA, Immunex requested that Sandoz Inc. provide further information.

ANSWER: The allegations contained in Paragraph 58 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

59. On November 16, 2015, Sandoz Inc. provided additional documents which it represented to relate to the manufacturing process for Defendants' biosimilar product.

ANSWER: The allegations contained in Paragraph 59 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

60. Notwithstanding issues with the timeliness and completeness of the information Sandoz Inc. had provided, in respect of 42 U.S.C. § 262(*l*)(3)(A), Immunex nevertheless provided to Sandoz Inc. on December 18, 2015 a list of patents for which a claim of infringement could be reasonably asserted based on Defendants' etanercept product.

ANSWER: The allegations contained in Paragraph 60 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

61. On January 27, 2016, Sandoz Inc. responded to Immunex's list of patents by stating that it no longer wished to follow the strictures of the BPCIA. Specifically, Sandoz Inc.

sent Immunex a 86-page letter stating its patent contentions but "agreeing" with Immunex's 42 U.S.C. § 262(*l*)(3)(A) list. Sandoz Inc. also stated it was "waiving" its right to receive a statement by Immunex pursuant to 42 U.S.C. § 262(*l*)(3)(C), and declared that negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5) were unnecessary. Sandoz Inc. then insisted that Immunex file an action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(6) within 30 days, *i.e.*, by February 26, 2016. Also on January 27, 2016, Sandoz Inc. provided additional documents which it represented provided even more information relating to the manufacturing process for Defendants' biosimilar product.

ANSWER: The allegations contained in Paragraph 61 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

62. On February 10, 2016, Immunex explained to Sandoz Inc. that its refusal to participate in negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5) was contrary to the text of the statute. Immunex also requested that Sandoz Inc. withdraw its refusal to participate in the statutory process set forth in 42 U.S.C. § 262(*l*)(4) and (5), and explained that Sandoz Inc.'s failure to do so implicated 42 U.S.C. § 262(*l*)(9), which authorizes the reference product sponsor, but not the subsection (k) applicant, to file a declaratory judgment action on patents that are or would be infringed by the biosimilar applicant (Sandoz Inc.).

ANSWER: The allegations contained in Paragraph 62 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

63. On February 17, 2016, Sandoz Inc. confirmed its refusal to participate in negotiations pursuant to 42 U.S.C. § 262(*l*)(4) and (5), and stated that it wished for patent litigation to begin as soon as possible. No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: The allegations contained in Paragraph 63 are directed to another Defendant and, therefore, require no response from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B).

64. Defendants have failed to participate, and thus, have not complied with the process defined in the statute that must precede an "immediate patent infringement action" under 42 U.S.C. § 262(*l*)(6). By refusing to participate in a timely and complete manner under the BPCIA, including by seeking to extinguish Immunex's ability to consider and respond to Sandoz Inc.'s contentions regarding the patents that Immunex had properly identified and entirely evading the negotiations specified in 42 U.S.C. § 262(*l*)(4) and (5), Sandoz Inc. has repudiated its obligations under the BPCIA. Thus, in addition to bringing an action under 35 U.S.C. § 271(e)(2)(C), Immunex—but not Defendants—pursuant to 42 U.S.C. § 262(*l*)(9) may bring a declaratory action on patents related to Defendants' biosimilar product.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 64.

V. THE PATENTS-IN-SUIT

A. The '182 and '522 Patents

65. In the late 1980s, Roche and Immunex scientists were early pioneers in isolating, characterizing, cloning, and sequencing p55 and p75 versions of the human TNF receptors, respectively.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 65.

66. Roche scientists were the first to clone and sequence the human p55 TNF receptor gene and determine the amino acid sequence of the receptor. They published the sequence of this receptor on April 20, 1990. *See* Loetscher et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," *Cell* 61:351-359 (April 20, 1990).

ANSWER: Sandoz GmbH admits that there is a publication entitled Loetscher, *et al*., *Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor*, Cell 61:351-359 (1990) that purports to identify the amino acid sequence of the human p55 TNF receptor. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 66, and on that basis denies these allegations.

67. Immunex scientists were the first to clone and sequence the p75 TNF receptor gene and determine the amino acid sequence of the receptor. They published the sequence of the human p75 TNF receptor later the same year. *See* Smith et al., "A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins," *Science* 248:1019-1023 (1989).

ANSWER: Sandoz GmbH admits that people other than the named inventors on the '182 and '522 patents were the first to clone and sequence the p75 TNF receptor gene and determine the amino acid sequence of the receptor. Sandoz GmbH further admits that there is a publication entitled Smith, *et al*., *A Receptor for Tumor Necrosis Factor Defines an Unusual Family of Cellular and Viral Proteins*, Science 248:1019-1023 (1990) that purports to identify the amino acid sequence of the human p75 TNF receptor, and that this publication was not authored by any named inventor of the '182 or '522 patents, but Sandoz GmbH denies that it was published in

1989. Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 67, and on that basis denies these allegations.

68. On August 31, 1990, Roche scientists filed European Patent Application No. 90116707.2, which disclosed and taught the novel concept of fusing of the extracellular fragment of the TNF receptors with a portion of the human immunoglobulin heavy chain *(i.e.*, all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain of said constant region). These Roche scientists also filed a United States patent application on September 10, 1990, which claimed priority to said European patent application.

ANSWER: Sandoz GmbH admits that EP Application No. 90116707.2 states that it was filed on August 31, 1990 and names Manfred Brockhaus, Reiner Gentz, Zlatko Dembic, Werner Lesslauer, Hansruedi Lotscher, and Ernst-Jurgen Schlaeger as inventors. Sandoz GmbH further admits that U.S. Patent Application No. 07/580,013 states that it was filed on September 10, 1990, purports to claim priority to EP Application No. 90116707.2, and names Manfred Brockhaus, Reiner Gentz, Zlatko Dembic, Werner Lesslauer, Hansruedi Lotscher, and Ernst-Jurgen Schlaeger as inventors. Sandoz GmbH denies the remaining allegations contained in Paragraph 68.

69. The ‘182 and ‘522 patents issued from applications that claim priority to the European patent application filed on August 31, 1990.

ANSWER: Sandoz GmbH admits that the ‘182 and ‘522 patents issued from U.S. Patent Application Nos. 08/444,790 and 08/444,791, respectively. Sandoz GmbH further admits that the faces of the ‘182 and ‘522 patents purport to claim priority to EP Application No. 90116707.2. Sandoz GmbH denies the remaining allegations contained in Paragraph 69.

70. The ‘182 patent is directed to a fusion protein incorporating a portion of the p75 TNF receptor and covers etanercept. The ‘522 patent is directed to nucleic acids, host cells, and methods of using such nucleic acids and host cells to make the p75 TNF receptor fusion protein.

ANSWER: Sandoz GmbH admits that the ‘182 patent is entitled “Human TNF Receptor Fusion

Protein" and the claims are generally directed to fusion proteins that specifically bind human TNF comprising or consisting of, inter alia, TNF-binding soluble fragments of an insoluble p75 human TNF receptor or the extracellular region of the insoluble p75 human TNF receptor. Sandoz GmbH further admits that the '522 patent is entitled "Human TNF Receptor" and the claims are generally directed to polynucleotides, host cells, and methods of making polynucleotides encoding proteins that consist of, inter alia, the extracellular region of an insoluble p75 human TNF receptor. Sandoz GmbH denies that the '182 or '522 patents describe either a p75 TNF receptor, a fusion protein comprising or consisting of any TNF receptor or fragments or portions thereof, or any method of making such a fusion protein. Sandoz GmbH denies that the named inventors on the '182 and '522 patents invented or possessed any TNF receptor fusion protein or method of making one, let alone a fusion protein that comprises or consists of the p75 TNF receptor or fragments or portions thereof. Sandoz GmbH denies the remaining allegations contained in Paragraph 70.

B. The '225, '605, and '631 Patents

71. In developing etanercept as a therapeutic, Immunex also developed and obtained patents directed toward using etanercept to treat psoriasis and/or psoriatic arthritis. The '225 patent, the '605 patent, and the '631 patent ("the Psoriasis Patents"), owned by Immunex, disclose and claim methods of using etanercept to treat psoriasis and/or psoriatic arthritis.

ANSWER: On information and belief, Sandoz GmbH admits that the '225, '605, and '631 patents are owned by Immunex Corporation and that the patents are generally directed to the treatment of one or more of the following conditions: psoriasis, ordinary psoriasis, plaque psoriasis, and/or psoriatic arthritis. Sandoz GmbH denies the remaining allegations contained in Paragraph 71.

72. Psoriasis is a chronic inflammatory disease of the skin and joints. It results in scaly growths on the skin of affected patients, which can be disfiguring and extremely uncomfortable.

ANSWER: Sandoz GmbH admits that psoriasis is a chronic inflammatory disease that can involve the skin, but denies that this is a complete characterization of psoriasis. Sandoz GmbH denies the remaining allegations contained in Paragraph 72.

73. Psoriatic arthritis is an inflammatory arthritis characterized by joint pain, stiffness, and swelling. It can cause to joint damage which limits daily activities.

ANSWER: Sandoz GmbH admits that psoriatic arthritis is an inflammatory arthritis characterized by joint paint, stiffness, and swelling, but denies that this is a complete characterization of psoriatic arthritis. Sandoz GmbH denies the remaining allegations contained in Paragraph 73.

74. In the late 1990s, there were no biologic therapies approved to treat psoriasis or psoriatic arthritis.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 74.

75. Dermatologists had used various other therapeutic approaches to treating psoriasis, such as methotrexate, psoralen and ultraviolet A radiation, and cyclosporine. However, each of these therapies was found to have serious side effects, such as liver damage, skin damage, and kidney damage, respectively, after they had been used for many years.

ANSWER: Sandoz GmbH admits that physicians have used methotrexate, psoralen and ultraviolet A radiation, and cyclosporine, among other treatments, to treat psoriasis, and that such treatments can have serious side effects, including liver damage, skin damage, and kidney damage, but denies that these were the only treatments physicians used to treat psoriasis. Sandoz GmbH denies the remaining allegations contained in Paragraph 75.

76. The Psoriasis Patents claim priority to a provisional application filed on August 11, 1999. The Psoriasis Patents also claim priority to non-provisional applications filed August 13, 1999, and June 23, 2000.

ANSWER: Sandoz GmbH admits that the ‘225, ‘605, and ‘631 patents purport to claim priority to Provisional Application No. 60/148,234 filed August 11, 1999 and U.S. Application Nos. 09/373,828, filed on August 13, 1999 and 09/602,351, filed on June 23, 2000. Sandoz GmbH

denies the remaining allegations contained in Paragraph 76.

77. As a general matter, the Psoriasis Patents contain claims to using etanercept to treat psoriasis and/or psoriatic arthritis, and further specify certain dosage regimes to follow.

ANSWER: Sandoz GmbH admits that the '225, '605, and '631 patents are generally directed to using etanercept to treat one or more of the following conditions: psoriasis, ordinary psoriasis, plaque psoriasis, and/or psoriatic arthritis and that some of the claims of those patents claim dosing regimens. Sandoz GmbH denies the remaining allegations contained in Paragraph 77.

78. The manner in which ENBREL® is commonly used to treat psoriasis (or psoriasis and psoriatic arthritis) today falls within the scope of the claims of the Psoriasis Patents.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz GmbH denies that the claims of the '225, '605, and/or '631 patents claim only the treatment of "psoriasis (or psoriasis and psoriatic arthritis)." Sandoz GmbH lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 78, and on that basis denies these allegations.

COUNT 1: INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

79. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-70 as if fully set forth herein.

80. The '182 patent, titled "Human TNF Receptor Fusion Protein," was duly and legally issued on November 22, 2011 by the United States Patent and Trademark Office ("USPTO"). A true and correct copy of the '182 patent is attached to this Complaint as Exhibit C.

ANSWER: Sandoz GmbH admits that the USPTO issued the '182 patent on November 22, 2011. Sandoz GmbH admits that Exhibit C to the Complaint appears to be a copy of the '182 patent. Sandoz GmbH denies that the '182 patent was duly and legally issued. Sandoz GmbH denies the remaining allegations contained in Paragraph 80.

81. The claims of the '182 patent cover etanercept and pharmaceutical compositions that are made from etanercept.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 81.

82. Defendants have infringed the '182 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16 and 50. Sandoz GmbH denies the remaining allegations contained in Paragraph 82.

83. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '182 patent to Sandoz pursuant to 42 U.S.C. § 262(*l*)(3)(A).

ANSWER: The allegations contained in Paragraph 83 are directed to another Defendant, therefore, no response is required from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies the allegations directed to it contained in Paragraph 83.

84. Defendants have known of the '182 patent since at least June 2013. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, offer to sell, and sell their biosimilar product within the United States before the expiration of the '182 patent and in violation of Immunex/AML and Roche's patent rights.

ANSWER: Sandoz GmbH admits that it has known of the '182 patent since at least June 2013. Sandoz GmbH admits that, in July 2015, Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States its etanercept product before expiration of the '182 patent. Sandoz GmbH denies the remaining allegations contained in Paragraph 84.

85. Immunex/AML and/or Roche will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '182 patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 85.

86. Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, upon FDA approval of Defendants' etanercept biosimilar product and before the expiration of the '182 patent, will cause injury to Immunex/AML and Roche, entitling them to damages or other monetary relief.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 86.

COUNT 2: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '182 PATENT UNDER 35 U.S.C. § 271(a)

87. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-70 as if fully set forth herein.

88. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to manufacture, use, import, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept).

ANSWER: Sandoz GmbH admits that Sandoz, Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States its etanercept product, and that Sandoz Inc.'s BLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Sandoz GmbH denies the remaining allegations contained in Paragraph 88.

89. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

ANSWER: Sandoz GmbH states that the FDA approved Sandoz Inc.'s aBLA on August 30, 2016.

90. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of § 262(*l*)(8), import and offer to sell or sell within the United States Defendants' etanercept biosimilar product, which will infringe one or more claims of the '182 patent under 35 U.S.C. § 271(a).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 90.

91. An actual controversy has arisen and now exists between the parties concerning

whether Defendants' etanercept biosimilar product has or will infringe one or more claims of the '182 patent.

ANSWER: Sandoz GmbH admits that there is an actual controversy concerning whether the '182 patent is infringed, valid, and enforceable. Sandoz GmbH denies the remaining allegations contained in Paragraph 91.

92. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 92.

93. Immunex/AML and Roche are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the ' 182 patent by making, using, offering to sell, or selling within the United States, or importing into the United States Defendants' etanercept biosimilar product before the expiration of the '182 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 93.

94. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States Defendants' etanercept biosimilar product before the expiration of the '182 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 94.

95. Defendants' manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Defendants' etanercept biosimilar product before the expiration of the '182 patent will cause injury to Immunex/AML and Roche, entitling them to damages under 35 U.S.C. § 284.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 95.

COUNT 3: INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

96. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-70 as if fully set forth herein.

97. The '522 patent, titled "Human TNF Receptor," was duly and legally issued on April 24, 2012 by the USPTO. A true and correct copy of the '522 patent is attached to this Complaint as Exhibit D.

ANSWER: Sandoz GmbH admits that the USPTO issued the '522 patent on April 24, 2012. Sandoz GmbH admits that Exhibit D to the Complaint appears to be a copy of the '522 patent. Sandoz GmbH denies that the '522 patent was duly and legally issued. Sandoz GmbH denies the remaining allegations of Paragraph 97.

98. The claims of the '522 patent cover, among other things, methods of making etanercept and certain materials used in such methods.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 98.

99. Defendants have infringed the '522 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16 and 50. Sandoz GmbH denies the remaining allegations contained in Paragraph 99.

100. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '522 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(l)(3)(A).

ANSWER: The allegations contained in Paragraph 100 are directed to another Defendant, therefore, no response is required from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies any allegations directed to it contained in Paragraph 100.

101. Defendants have known of the '522 patent since at least June 2013. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product that was manufactured by the methods of the '522 patent, with the intent to import, offer to sell, and sell their biosimilar product within the United States before the expiration of the '522 patent and in violation of Immunex/AML and Roche's patent rights.

ANSWER: Sandoz GmbH admits that it has known of the '522 patent since at least June 2013. Sandoz GmbH admits that, in July 2015, Sandoz Inc. filed BLA No. 761042 pursuant to 42

U.S.C. § 262(k) to obtain FDA approval and to offer to sell, sell, and import into the United States Sandoz Inc.'s etanercept product before expiration of the '522 patent. Sandoz GmbH denies the remaining allegations contained in Paragraph 101.

102. Immunex/AML and Roche will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '522 patent. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 102.

103. Defendants' commercial manufacture of Defendants' etanercept product, and their subsequent importation for sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product and before the expiration of the '522 patent will cause injury to Immunex/AML and Roche, entitling them to damages or other monetary relief.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 103.

COUNT 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '522 PATENT UNDER 35 U.S.C. § 271(g)

104. Immunex/AML and Roche incorporate by reference paragraphs 1-70 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-70 as if fully set forth herein.

105. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, manufacture Defendants' etanercept product according to the process described in their aBLA and import and offer to sell or sell within the United States Defendants' etanercept biosimilar product made by such process, which will infringe the method claims of the '522 patent under 35 U.S.C. § 271(g).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 105.

106. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

ANSWER: Sandoz GmbH states that the FDA approved Sandoz Inc.'s aBLA on August 30, 2016.

107. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(*l*)(8), import and offer to sell or sell within the United States Defendants' etanercept biosimilar product, which will infringe one or more claims of the '522 patent under 35 U.S.C. § 271(g).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 107.

108. The etanercept made by Defendants' process that infringes the '522 patent is the essential active ingredient of Defendants' biological drug product. On information and belief, there is no subsequent process that materially changes that active ingredient, including during any fill and finish of the biological product.

ANSWER: Sandoz GmbH admits that the active ingredient in the product that is the subject of BLA No. 761042 is etanercept. Sandoz GmbH denies the remaining allegations contained in Paragraph 108.

109. An actual controversy has arisen and now exists between the parties concerning whether Defendants' etanercept biosimilar product has infringed or will infringe one or more claims of the '522 patent.

ANSWER: Sandoz GmbH admits that there is an actual controversy concerning whether the '522 patent is infringed, valid, and enforceable. Sandoz GmbH denies the remaining allegations contained in paragraph 109.

110. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 110.

111. Immunex/AML and Roche are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '522 patent by making Defendants' etanercept biosimilar product and importing it into the United States for sale in the United States, before the expiration of the '522 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 111.

112. Immunex/AML and Roche do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the

‘522 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 112.

113. Defendants’ making, importing, and selling within the United States of Defendants’ etanercept biosimilar product before the expiration of the ‘522 patent will cause Immunex/AML and Roche injury, entitling them to damages under 35 U.S.C. § 284.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 113.

COUNT 5: INFRINGEMENT OF THE ‘225 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

114. Immunex/AML incorporate by reference paragraphs 1-113 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-113 as if fully set forth herein.

115. The ‘225 patent, titled “Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders” was duly and legally issued on March 29, 2011 by the USPTO. A true and correct copy of the ‘225 patent is attached to this Complaint as Exhibit E.

ANSWER: Sandoz GmbH admits that the USPTO issued the ‘225 patent on March 29, 2011. Sandoz GmbH admits that Exhibit E to the Complaint appears to be a copy of the ‘225 patent. Sandoz GmbH denies that the ‘225 patent was duly and legally issued. Sandoz GmbH denies the remaining allegations contained in Paragraph 115.

116. The ‘225 patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept.

ANSWER: Sandoz GmbH incorporates herein its response to Paragraph 77. Sandoz GmbH denies the remaining allegations contained in Paragraph 116.

117. Defendants have infringed the ‘225 patent by submitting an aBLA referencing Immunex’s ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16 and 50. Sandoz GmbH denies the remaining allegations contained in Paragraph 117.

118. With the intent to infringe the '225 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for the treatment of psoriasis or psoriatic arthritis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®'s labeling that instructs physicians and patients to administer etanercept subcutaneously for treatment of psoriasis or psoriatic arthritis in specific dosages, which is covered by the '225 patent.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16, 52, and 55. Sandoz GmbH admits that Sandoz Inc.'s proposed label contains indications for the use of its product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for the treatment of psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for treatment of psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 118.

119. On information and belief, Defendants knew of the '225 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, market, offer to sell, and sell their biosimilar product for psoriasis and/or psoriatic arthritis within the United States before the expiration of the '225 patent and in violation of Immunex/AML's patent rights.

ANSWER: Sandoz GmbH admits that it knew of the '225 patent before July 2015. Sandoz GmbH admits that, in July 2015, Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the United States its etanercept product before expiration of the '225 patent. Sandoz GmbH admits that Sandoz Inc.'s proposed label contains indications for the use of its product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for the

treatment of psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 119.

120. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '225 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(l)(3)(A).

ANSWER: The allegations contained in Paragraph 120 are directed to another Defendant, therefore, no response is required from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies any allegations directed to it contained in Paragraph 120.

121. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '225 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 121.

122. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for use with psoriasis and/or psoriatic arthritis before the expiration of the '225 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 122.

COUNT 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '225 PATENT UNDER 35 U.S.C. § 271(b)

123. Immunex/AML incorporate by reference paragraphs 1-122 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-122 as if fully set forth herein.

124. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept), for treating psoriasis and psoriatic arthritis.

ANSWER: Sandoz GmbH admits that Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the

United States Sandoz Inc.'s etanercept product, and that Sandoz Inc.'s BLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Sandoz GmbH admits that Sandoz Inc.'s proposed label contains indications for the use of its product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for treating psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for treating psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 124.

125. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

ANSWER: Sandoz GmbH states that the FDA approved Sandoz Inc.'s aBLA on August 30, 2016.

126. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of § 262(l)(8), import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis, which use by physicians and patients will infringe one or more claims of the '225 patent under 35 U.S.C. § 271(b).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 126.

127. An actual controversy has arisen and now exists between the parties concerning whether Defendants will induce infringement by physicians and patients of the '225 patent by their marketing and sales of their etanercept biosimilar product for psoriasis and/or psoriatic arthritis.

ANSWER: Sandoz GmbH admits that there is an actual controversy concerning whether the '225 patent is infringed, valid, and enforceable. Sandoz GmbH denies the remaining allegations contained in paragraph 127.

128. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under

42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 128.

129. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed, will infringe, or will induce infringement of one or more claims of the '225 patent by marketing, offering to sell, or selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis and/or psoriatic arthritis before the expiration of the '225 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 129.

130. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '225 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 130.

131. Defendants' marketing, offer for sale, or sale within the United States of Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before the expiration of the '225 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 131.

COUNT 7: INFRINGEMENT OF THE '605 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

132. Immunex/AML incorporate by reference paragraphs 1-131 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-131 as if fully set forth herein.

133. The '605 patent, titled "Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders" was duly and legally issued on February 21, 2012 by the USPTO. A true and correct copy of the '605 patent is attached to this Complaint as Exhibit F.

ANSWER: Sandoz GmbH admits that the USPTO issued the '605 patent on February 21, 2012. Sandoz GmbH admits that Exhibit F to the Complaint appears to be a copy of the '605 patent. Sandoz GmbH denies that the '605 patent was duly and legally issued. Sandoz GmbH denies the remaining allegations contained in Paragraph 133.

134. The '605 patent is generally directed to methods of treating psoriasis by administering etanercept.

ANSWER: Sandoz GmbH incorporates herein its response to Paragraph 77. Sandoz GmbH denies the remaining allegations contained in Paragraph 134.

135. Defendants have infringed the '605 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject of that application.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16 and 50. GmbH denies the remaining allegations contained in Paragraph 135.

136. With the intent to infringe the '605 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for the treatment of psoriasis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®'s labeling that instructs physicians and patients to administer etanercept for treating psoriasis in specific dosages, which is covered by the '605 patent.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16, 52, and 55. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for the treatment of psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for treating psoriasis." Sandoz GmbH denies that the '605 patent covers the administration of etanercept for treating "psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 136.

137. On information and belief, Defendants knew of the '605 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, market, offer to sell, and sell their biosimilar product for treating psoriasis within the United States before the expiration of the '605 patent and in violation of Immunex/AML's patent rights.

ANSWER: Sandoz GmbH admits that it knew of the '605 patent before July 2015. Sandoz GmbH admits that, in July 2015, Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the United

States Sandoz Inc.'s etanercept product before expiration of the '605 patent. Sandoz GmbH denies that Sandoz Inc. is seeking approval for the use of etanercept to treat "psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 137.

138. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '605 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(l)(3)(A).

ANSWER: The allegations contained in Paragraph 138 are directed to another Defendant, therefore, no response is required from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies any allegations directed to it contained in Paragraph 138.

139. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '605 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 139.

140. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for treating psoriasis and before the expiration of the '605 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 140.

COUNT 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '605 PATENT UNDER 35 U.S.C. § 271(b)

141. Immunex/AML incorporate by reference paragraphs 1-140 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-140 as if fully set forth herein.

142. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a biosimilar version of ENBREL® (etanercept), for treating psoriasis.

ANSWER: Sandoz GmbH admits that Sandoz Inc. filed BLA No. 761042 pursuant to 42

U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the United States Sandoz Inc.'s etanercept product, and that Sandoz Inc.'s BLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). Sandoz GmbH denies that Sandoz Inc. is seeking approval for the use of etanercept to treat "psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 142.

143. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and that Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

ANSWER: Sandoz GmbH states that the FDA approved Sandoz Inc.'s aBLA on August 30, 2016.

144. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(*l*)(8), import, market, offer to sell, or sell within the United States the Sandoz etanercept biosimilar product for treating psoriasis, which use by physicians and patients will infringe one or more claims of the '605 patent under 35 U.S.C. § 271(b).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 144.

145. An actual controversy has arisen and now exists between the parties concerning whether Sandoz will induce infringement by physicians and patients of the '605 patent by their marketing and sales of Defendants' etanercept biosimilar product for psoriasis.

ANSWER: Sandoz GmbH admits that there is an actual controversy concerning whether the '605 patent is infringed, valid, and enforceable. Sandoz GmbH denies the remaining allegations contained in Paragraph 145.

146. Defendants also have failed to complete the actions required of them under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 146.

147. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '605 patent by marketing, offering to sell, or

selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis before the expiration of the '605 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 147.

148. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '605 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 148.

149. Defendants' marketing, offer for sale, or sale within the United States of the Sandoz etanercept biosimilar product for treating psoriasis before the expiration of the '605 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 149.

COUNT 9: INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)

150. Immunex/AML incorporate by reference paragraphs 1-149 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-149 as if fully set forth herein.

151. The '631 patent, titled "Soluble Tumor Necrosis Factor Receptor Treatment of Medical Disorders" was duly and legally issued on May 13, 2014 by the USPTO. A true and correct copy of the '631 patent is attached to this Complaint as Exhibit G.

ANSWER: Sandoz GmbH admits that the USPTO issued the '631 patent on May 13, 2014. Sandoz GmbH admits that Exhibit G to the Complaint appears to be a copy of the '631 patent. Sandoz GmbH denies that the '631 patent was duly and legally issued. Sandoz GmbH denies the remaining allegations contained in Paragraph 151.

152. The '631 patent is generally directed to methods of treating psoriasis and/or psoriatic arthritis by administering etanercept.

ANSWER: Sandoz GmbH incorporates herein its response to Paragraph 77. Sandoz GmbH denies the remaining allegations contained in Paragraph 152.

153. Defendants have infringed the '631 patent by submitting an aBLA referencing Immunex's ENBREL® product and seeking FDA approval under 42 U.S.C. § 262(k) to manufacture, import, offer to sell, or sell within the United States the product that is the subject

of that application.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16 and 50. Sandoz GmbH denies the remaining allegations contained in Paragraph 153.

154. With the intent to infringe the '631 patent, Defendants submitted their aBLA seeking FDA approval under 42 U.S.C. § 262(k) to market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for the treatment of psoriasis and psoriatic arthritis. On information and belief, Defendants conducted clinical trials of their etanercept biosimilar product for the psoriasis indication only. On information and belief, Defendants copied ENBREL®'s labeling that instructs physicians and patients to administer etanercept subcutaneously for treatment of psoriasis or psoriatic arthritis in specific dosages, which is covered by the '631 patent.

ANSWER: Sandoz GmbH incorporates herein its responses to Paragraphs 16, 52, and 55. Sandoz GmbH admits that Sandoz Inc.'s proposed label contains indications for the use of its product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for the treatment of psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for treatment of psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 154.

155. On information and belief, Defendants knew of the '631 patent before July 2015. Despite such knowledge, Defendants nonetheless filed their aBLA with the FDA in July 2015 seeking approval of Defendants' etanercept biosimilar product, with the intent to import, market, offer to sell, and sell their biosimilar product for psoriasis and/or psoriatic arthritis within the United States before the expiration of the '631 patent and in violation of Immunex/AML's patent rights.

ANSWER: Sandoz GmbH admits that it knew of the '631 patent before July 2015. Sandoz GmbH admits that, in July 2015, Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the United States Sandoz Inc.'s etanercept product before expiration of the '631 patent. Sandoz GmbH admits that Sandoz Inc's proposed label contains indications for the use of Sandoz Inc.'s product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis,

ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 155.

156. On December 18, 2015, Immunex, as the reference product sponsor for ENBREL®, identified the '631 patent to Sandoz Inc. pursuant to 42 U.S.C. § 262(l)(3)(A).

ANSWER: The allegations contained in Paragraph 156 are directed to another Defendant, therefore, no response is required from Sandoz GmbH. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz GmbH denies any allegations directed to it contained in Paragraph 156.

157. Immunex/AML will be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '631 patent. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 157.

158. Defendants' commercial marketing, offer for sale, or sale within the United States, upon FDA approval of Defendants' etanercept biosimilar product for use in psoriasis or psoriatic arthritis and before the expiration of the '631 patent, will cause injury to Immunex/AML, entitling Immunex/AML to damages or other monetary relief.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 158.

COUNT 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(b)

159. Immunex/AML incorporate by reference paragraphs 1-158 as if fully set forth herein.

ANSWER: Sandoz GmbH incorporates its responses to paragraphs 1-158 as if fully set forth herein.

160. Defendants have sought FDA approval under 42 U.S.C. § 262(k) to import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product, a

biosimilar version of ENBREL® (etanercept), for treating psoriasis and/or psoriatic arthritis.

ANSWER: Sandoz GmbH admits that Sandoz Inc. filed BLA No. 761042 pursuant to 42 U.S.C. § 262(k) to obtain FDA approval and to market, offer to sell, sell, and import into the United States Sandoz Inc.'s etanercept product, and that Sandoz Inc.'s BLA meets the requirements of 42 U.S.C. § 262(k)(2)(A)(i). On information and belief, Sandoz GmbH admits that Sandoz Inc.'s proposed label contains indications for the use of its product to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Sandoz GmbH denies that Sandoz Inc. is seeking FDA approval "for treating psoriasis" and that either Sandoz Inc.'s proposed label or ENBREL®'s label instructs physicians and patients to administer etanercept "for treating psoriasis." Sandoz GmbH denies the remaining allegations contained in Paragraph 160.

161. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt. On information and belief, Defendants believe that the FDA may act upon Defendants' aBLA as soon as May 2016, and Defendants will be able to pay the user fee prescribed under the Prescription Drug User Fee Act by that time.

ANSWER: Sandoz GmbH states that the FDA approved Sandoz Inc.'s aBLA on August 30, 2016.

162. On information and belief, Defendants intend to, and will immediately and imminently upon FDA licensure of Defendants' aBLA, notwithstanding the clear requirements of 42 U.S.C. § 262(/)(8), import, market, offer to sell, or sell within the United States Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis, which use by physicians and patients will infringe one or more claims of the '631 patent under 35 U.S.C. § 271(b).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 162.

163. An actual controversy has arisen and now exists between the parties concerning whether Defendants will induce infringement by physicians and patients of the '631 patent by their marketing and sales of Defendants' etanercept biosimilar product for psoriasis and/or psoriatic arthritis.

ANSWER: Sandoz GmbH admits there is an actual controversy concerning whether the '631

patent is infringed, valid, and enforceable. Sandoz GmbH denies the remaining allegations contained in Paragraph 163.

164. Defendants also have failed to complete the actions required of Defendants under 42 U.S.C. § 262(*l*)(4) and (5) by failing to engage in negotiation and exchange of patent lists under 42 U.S.C. § 262(*l*)(4) and 262(*l*)(5). No list of patents for Defendants' etanercept biosimilar product was generated as described in 42 U.S.C. § 262(*l*)(4) or as described in 42 U.S.C. § 262(*l*)(5).

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 164.

165. Immunex/AML are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '631 patent by marketing, offering to sell, or selling within the United States Defendants' etanercept biosimilar product for treatment of psoriasis and/or psoriatic arthritis before the expiration of the '631 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 165.

166. Immunex/AML do not have an adequate remedy at law and are entitled to injunctive relief prohibiting Defendants from making, importing into, and selling within the United States Defendants' etanercept biosimilar product before the expiration of the '631 patent.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 166.

167. Defendants' marketing, offer for sale, or sale within the United States of Defendants' etanercept biosimilar product for treating psoriasis and/or psoriatic arthritis before the expiration of the '631 patent will cause Immunex/AML injury, entitling them to damages under 35 U.S.C. § 284.

ANSWER: Sandoz GmbH denies the allegations contained in Paragraph 167.

ANSWER TO PRAYER FOR RELIEF

Sandoz GmbH denies that Plaintiffs are entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz GmbH bears the burden of proof as to any of them, Sandoz GmbH, on information and belief, asserts the following affirmative defenses:

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

2. The ‘182, ‘522, ‘225, ‘605, and ‘631 patents and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation, including obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(No Direct Infringement)

3. Sandoz GmbH has not, does not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ‘182, ‘522, ‘225, ‘605, and/or ‘631 patents.

FOURTH AFFIRMATIVE DEFENSE
(No Indirect Infringement)

4. Sandoz GmbH has not, does not, and will not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claim of the ‘225, ‘605, and/or ‘631 patents.

FIFTH AFFIRMATIVE DEFENSE
(Unenforceability due to Prosecution Laches)

5. The ’182 and ‘522 patents are unenforceable on the ground of prosecution laches, because the applicants engaged in an unreasonable and unexplained delay in prosecuting those patents, which resulted in prejudice to Sandoz GmbH, other drug manufacturers, and the public at large.

6. The ’182 and ‘522 patents each purport to claim priority to U.S. Patent Application No. 07/580,013 (“the ‘013 application”), filed September 10, 1990, as well as earlier applications filed in Europe. In addition, they stem from U.S. Patent Application No.

08/095,640 ("the '640 application"), which was filed July 21, 1993 as a continuation of the '013 application, and is the application from which U.S. Patent No. 5,610,279 issued.

7. The '182 patent issued from U.S. Patent Application No. 08/444,790 ("the '790 application"), filed on May 19, 1995, as a divisional of the '640 application. The '522 patent issued from U.S. Patent Application No. 08/444,791 ("the '791 application"), also filed on May 19, 1995, and also as a divisional of the '640 application. Both applications were filed only one month before the Uruguay Round Agreements Act ("GATT"), Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified at 35 U.S.C. § 154(a)(2)), went into effect in June 1995. Because they issued from pre-GATT applications, the '182 and '522 patents expire seventeen years after the patents issued, on November 22, 2028 for the '182 patent and April 24, 2029 for the '522 patent. Also because these were pre-GATT applications, they were never published, and their existence remained hidden from the public until the '182 and '522 patents issued in 2011 and 2012.

8. On information and belief, in 1990 when the '013 application was filed, the named inventors of the '182 and '522 patents were employed by, or working on behalf of, Plaintiff Roche to develop a fusion protein containing part or all of the p55 TNFR for potential FDA approval.

9. The named inventors of the '182 and '522 patents did not invent a fusion protein containing part or all of the p75 TNFR. Moreover, on information and belief, despite their development efforts, neither the named inventors nor Roche ever obtained FDA approval for either a p55 or a p75 TNFR fusion protein to treat any condition.

10. The prosecution of the '790 and '791 applications and their parent applications, the '013 and '640 applications, make clear that Roche was primarily pursuing claims directed to

the p55 protein, because that is what the inventors were claiming to have invented. There is no disclosure in any of the '013, '640, '790, or '791 applications, as filed, of the complete amino acid sequence of the p75 TNFR or the claimed "extracellular region" of the p75 TNFR, nor is there any working example of any fusion protein containing part or all of the p75 TNFR.

11. Moreover, the '790 and '791 applications from which the '182 and '522 patents issued originally included only claims directed to the p55 TNFR. Indeed, during prosecution of the '640 application, the PTO issued a restriction requirement, which required Roche to select one of multiple distinct inventions for further prosecution in that application. Among the selections Roche was required to make, was a selection of claims directed to either the p55 or p75 TNFR. As a result of this restriction requirement, Roche filed the '790 and the '791 divisional applications, stating in both that it selected the p55 TNFR. In response to this restriction requirement, Roche never filed a divisional application at any point in which it selected the p75 TNFR. Instead, Roche subsequently attempted to insert claims directed to the p75 TNFR in the pending, pre-GATT '790 and '791 applications, which resulted in significant delay in the prosecution of those applications.

12. On information and belief, at the same time Roche was working on the p55 TNFR protein in 1990, people employed by or working on behalf of Immunex were developing a fusion protein containing part or all of the p75 TNFR. Immunex obtained several patents based on this work, including U.S. Patent Nos. 5,395,760 and 5,605,690, which were generally directed to the p75 TNFR and fusion proteins comprising the p75 TNFR, and covered etanercept. The '760 patent expired in 2012, and the '690 patent expired in 2014.

13. Immunex also filed patent applications for the '225, '605, and '631 patents, among others, in 1999. These applications were filed post-GATT, so the patents expire 20 years

after the 1999 filing date in 2019, nearly ten years before the ‘182 and ‘522 patents expire.

14. On information and belief, when each of the ‘013, ‘640, ‘790, and ‘791 applications were filed, Immunex held no rights to all or part of any of those applications. On information and belief, sometime before 2005 and after Roche’s efforts to develop a p55 TNFR protein ended, Immunex licensed the ‘790 and ‘791 applications from Roche, and Immunex’s attorneys assumed responsibility for prosecution of those applications.

15. It was not until Immunex assumed responsibility for prosecuting the ‘790 and ‘791 applications, while simultaneously pursuing claims in the ‘225, ‘605, and ‘631 applications to uses of etanercept, that Immunex began in earnest to prosecute claims directed to the p75 protein in the ‘790 and ‘791 applications. For example, claims directed to a p75 TNFR fusion protein were not presented in the prosecution of the ‘790 application until January 12, 2005, nearly ten years after the ‘790 application was filed. Claims specifically directed to the p75 TNFR were not presented in the ‘791 application until 2000, five years after the ‘791 application was filed.

16. The delay in prosecuting claims directed to the p75 TNFR was unreasonable and unjustified because, among other things, Roche should have filed a divisional application containing those claims in response to the PTO’s original restriction requirement in the ‘640 application. Instead, Roche and then Immunex maintained claims that fell outside of that restriction requirement in the ‘790 and ‘791 applications, which resulted in (1) those applications being unpublished until the patents issued in 2011 and 2012 and (2) the patents expiring 17 years after issuance rather than 20 years after filing of an application.

17. Due to the unreasonable delays in prosecuting the p75 protein claims, the ’182 and ‘522 patents issued over two decades after the filing date of the ‘013 application and will not

expire until almost forty years after that date.

18. Sandoz Inc. began developing its etanercept product in 2004, while the '790 and '791 applications were being prosecuted unbeknownst to Sandoz Inc., or other members of the public, expecting that the patents Immunex owned that covered etanercept would expire by the time Sandoz Inc. was ready to market its product. Since that time, Sandoz Inc. has devoted substantial resources to developing its etanercept product in the reasonable belief that putative patent coverage on the etanercept protein would expire no later than 2014. Sandoz Inc. has been seriously prejudiced by assertion of the long-delayed claims of the '182 and '522 patents.

19. During the prosecution of the '790 and '791 applications, Sandoz Inc. began development on its etanercept product, with the reasonable and justified expectation that it would be able to market that product free of patent infringement liability upon the expiration of the patents listed in the label for ENBREL®. Accordingly, Sandoz Inc., among others, acquired "intervening rights" during the period of delay. The claims of the '182 and '522 patents are, therefore, unenforceable against Sandoz Inc. due to prosecution laches.

SIXTH AFFIRMATIVE DEFENSE
(No Equitable Relief)

20. Plaintiffs are not entitled to preliminary and/or permanent equitable relief.

SEVENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

21. Sandoz GmbH's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

OTHER AFFIRMATIVE DEFENSES RESERVED

Sandoz GmbH reserves the right to assert any other defenses that discovery may reveal.

RESERVATION OF RIGHTS

As Sandoz GmbH's investigation is ongoing and discovery has not yet taken place, Sandoz GmbH is without sufficient information regarding the existence or non-existence of other facts or acts that would constitute a defense to Plaintiffs' claims of patent infringement or that would establish the invalidity and/or unenforceability of the '182, '522, '225, '605, and '631 patents, including additional prior art or related patents. Sandoz GmbH hereby gives notice that it may assert facts or acts which tend to establish noninfringement, invalidity, unenforceability, or which otherwise constitute a defense under Title 35 of the United States Code as information becomes available to Sandoz GmbH in sufficient detail to assert such a defense.

PRAYER FOR RELIEF

WHEREFORE, Sandoz GmbH requests (a) that Plaintiffs' complaint be dismissed with prejudice and judgment be entered in favor of Sandoz GmbH; (b) a declaration that this case is exceptional under 35 U.S.C. § 285 entitling Sandoz GmbH to relief under that statute; and (c) an award of such other and further relief to Sandoz GmbH that the Court deems just and proper.

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Dated: October 27, 2016

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DEMAND FOR A JURY TRIAL

Sandoz GmbH hereby demands a jury trial on all issues so triable.

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ Melissa Steedle Bogad
Melissa Steedle Bogad
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Dated: October 27, 2016

CERTIFICATION OF SERVICE

I certify that on the 27th day of October, 2016, a true and correct copy of the foregoing **DEFENDANT SANDOZ GMBH'S ANSWER, AFFIRMATIVE DEFENSES, AND DEMAND FOR JURY TRIAL** was served upon all counsel of record by ECF and e-mail.

s/ Melissa Steedle Bogad
Melissa Steedle Bogad
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Dated: October 27, 2016